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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/019,506
Filing Date: May 10, 2002
Appellant(s): ELLIOTT ET AL.

Philip A. Dubois
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 2, 2006 appealing from the Office action mailed June 2, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct. However, the appellant did not mention that an election of species requirement was issued in this application in the paper dated July 14, 2004. In response to this election of species requirement, the appellant elected c) cardiovascular disease. Thus, at the time, the claims have only been examined in regards to these elected species.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Yoshikawa et al., *Enzymatic release of Pro-Beta-Casomorphin-9 and Beta-Casomorphin-9 from Bovine Beta-Casein*, Department of Food Science and Technology, Kyoto University (1994) pp. 38-42.

6,054,128	Wakat	04-2000
5,965,615	Kalvinsh et al.	10-1999
6,555,551	Spireas	04-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 28-32 and 37-45 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshikawa et al., (*Enzymatic release of Pro-Beta-Casomorphin-9 and Beta-Casomorphin-9 from Bovine Beta-Casein*, Department of Food Science and Technology, Kyoto University (1994) pp. 38-42) in view of Wakat (US 6,054,128) and Kalvinsh et al. (US 5,965,625) and Spireas (US 6,555,551).

Appellant claims a composition and/or method comprising an immunomodulating component (i.e. beta-casomorphin-9 or A2 beta-casein) and a fortifying compound to reduce the incidence of a population with cardiovascular disease. The fortifying compound is selected from betaine, cobalamin, folic acid or pyridoxine.

Yoshikawa et al. teach (see, e.g. entire article) that an immunomodulating component such as beta-casomorphin-9 are inhibitors of the Angiotensin Converting Enzyme (ACE) which is well known in the art to cause hypertension or heart failure. Spireas (see, e.g. column 1 lines

21-24) teaches that ACE inhibitors are useful for the treatment of cardiovascular disorders. Therefore, a person of ordinary skill in the art would be motivated to use the ACE inhibitor beta-casomorphin 9 to treat cardiovascular disorders. Yoshikawa et al and Spireas, however, do not teach that the claimed fortifying compounds can treat cardiovascular diseases.

Wakat benefically teaches (see, e.g. column 6 lines 41-56) fortifying compounds such as vitamin B6 (Pyridoxine), vitamin B12 (Cobalamin) and folic acid can treat cardiovascular disorders.

Kalvinsh et al. benefically teach (see, e.g. abstract) a fortifying compound such as betaine can treat cardiovascular disorder such as cardiopathy.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Yoshikawa et al.'s and Spireas's teachings of beta-casomorphin-9 for treating cardiovascular disease to include the beneficial teachings of Wakat and Kalvinsh et al. that the fortifying compounds also treat cardiovascular disease because the combined teachings of combining the two claimed active ingredients of an immunomodulating component and a fortifying compound would create an improved composition to reduce the incidence of population with cardiovascular disease. As discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose...".

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention made, especially in the absence of evidence to the contrary.

{Please note for claims 29-31, the patentablility of a product does not depend upon its method of production. If the product in a product-by-process claim is the same or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process." (see, e.g. MPEP 2113)}

(10) Response to Argument

In regards to the 35 U.S.C. 103(a) rejection based on the combination of Yoshikawa et al.,*Enzymatic release of Pro-Beta-Casomorphin-9 and Beta-Casomorphin-9 from Bovine Beta-Casein*, Department of Food Science and Technology, Kyoto University (1994) pp. 38-42) in view of Wakat (US 6,054,128) and Kalvinsh et al. (US 5,965,625) and Spireas (US 6555551), appellant argues Yoshikawa et al. fail to disclose or suggest utilizing these compounds in a dietary supplement. As to the Wakat and Kalvinsh et al. publications, appellants believe that these publications fail to remedy the deficiencies of Yoshikakwa et al. and Spireas for reference purpose to be utilized as a dietary supplement. Thus, appellants respectfully submit that the proposed combination of references fails to disclose or suggest the claimed dietary supplement or methods of using the claimed supplement.

The examiner disagree with the appellant's argument because the Yoshikawa et al. reference, the Wakat reference and the Kalvinsh reference each teaches the claimed invention's active ingredients are pharmaceutical active ingredients that can be administered orally to a subject. Furthermore, Wakat reference alone also teaches that the claimed fortifying compounds' active ingredient of vitamin B6, vitamin B12 and folic acid are orally administered as dietary supplements. Thus, since each reference teaches the claimed active ingredients as orally administered pharmaceuticals and/or a dietary supplement, one of ordinary skill in the art

would know that pharmaceuticals administered orally within the subject body would also serves as a dietary supplement when administered within the body.

The appellant also argues that the Office Action cites to Spireas as teaching that ACE inhibitors are useful for the treatment of cardiovascular disorders. While Spireas does teach that ACE inhibitors can be used to treat cardiovascular disorders, Spireas also teaches that "it has been widely observed that ACE inhibitors are susceptible to breakdown, especially due to degradation and/or cyclization between the time of manufacture and the time of desired usage." As a result, Spireas specifically teaches that enalapril maleate, quinapril hydrochloride and similar salts, should be used to provide stable formulations. Spireas does not teach disclose nor suggest that the claimed immunomodulating components can be used in a stable formulation. In fact, one skilled in the art would be lead away from the claimed invention in view of the teaching of Spireas in that the ACE inhibitors are susceptible to breakdown.

The examiner disagrees with the appellant's argument because the Spireas reference does not teach the breakdown of an ACE inhibitor peptide such as beta-casomorphine-9 or A2 beta-casein. Appellant stated as taught by Spireas that ACE inhibitors such as enalapril maletate, quinapril hydrochloride and similar salts may breakdown between the time of manufacture and the time of desired usage. However, the compounds that appellant mentioned above are not ACE inhibitor peptides like the ACE inhibitor peptides of beta-casomorphin-9 or A2 beta-casein. Thus, since appellant only referenced non ACE inhibitor peptides may breakdown between the time of manufacture and the time of desired usage, one of ordinary skill in the art can not assume that ACE inhibitor peptides of beta-casomorphin-9 or A2 beta-casein will break down between the time of manufacture and the time of desired

usage, especially in the absence of evidence to the contrary. Thus, Spireas is not considered to teach away from using ACE inhibitors to treat cardiovascular disease. Furthermore, appellants' method claims are directed towards a method for reducing the risk of developing cardiovascular disease. Thus, the individual treated in the method claims does not necessarily have cardiovascular disease. The individual treated need only be at risk for developing the disease. Any individual can be at risk for developing cardiovascular disease. Thus, the claimed method is carried out simply by the administration of the claimed immunomodulating components with the claimed fortifying components.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Susan D. Coe
4-17-06
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PRIMARY EXAMINER

Randall O Winston
April 12, 2006

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